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APPLICATION NO.	FILIN	G DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/747,715	12/26/2003		Michael Christopher Montalto	133658-2	5857
6147	7590	12/14/2005		EXAMINER	
		COMPANY	JONES, DAMERON LEVEST		
GLOBAL R PATENT DO		BLDG. K1-4A59	)	ART UNIT	PAPER NUMBER
NISKAYUN	IA, NY 123	09	1618		

DATE MAILED: 12/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)				
Office A.A. a. Comment		10/747,715	MONTALTO ET AL.				
	Office Action Summary	Examiner	Art Unit				
		D. L. Jones	1618				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).							
Status							
1)	Responsive to communication(s) filed on						
·		is action is non-final.					
3)[	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Dispositi	on of Claims						
4)⊠	4)⊠ Claim(s) <u>1-57</u> is/are pending in the application.						
	4a) Of the above claim(s) is/are withdrawn from consideration.						
5)	5) Claim(s) is/are allowed.						
6)[	6) Claim(s) is/are rejected.						
7)	7) Claim(s) is/are objected to.						
8)🖾	Claim(s) <u>1-57</u> are subject to restriction and/or	r election requirement.					
Applicati	on Papers						
9) The specification is objected to by the Examiner.							
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).							
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
Priority u	ınder 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:							
	1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No							
3. Copies of the certified copies of the priority documents have been received in this National Stage							
application from the International Bureau (PCT Rule 17.2(a)).							
* See the attached detailed Office action for a list of the certified copies not received.							
•44							
Attachment	• *	∆	(DTO 442)				
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date							
Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)   Notice of Informal Patent Application (PTO-152)   Paper No(s)/Mail Date   6)   Other:							

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## **RESTRICTION INTO GROUPS**

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group (1) Claims 1-7 and 12, drawn to <u>non-labeled</u> compounds of independent claim 1 wherein X is oxygen, classified in class 549, subclass 200.

Group (2) Claims 1, 2, and 7, drawn to <u>non-labeled</u> compounds of independent claim 1 wherein X is nitrogen, classified in class 540, subclass 1.

Group (3) Claims 1, 2, and 7, drawn to <u>non-labeled</u> compounds of independent claim 1 wherein X is sulfur, classified in class 549, subclass 1.

Group (4) Claims 1-26, drawn to <u>radiolabeled</u> compounds of independent claim 1 wherein X is oxygen, classified in class 424, subclass 1.65.

Group (5) Claims 1, 2, 7-11, 17, 18, and 23-26, drawn to <u>radiolabeled</u> compounds of independent claim 1 wherein X is nitrogen, classified in class 424, subclass 1.65.

Group (6) Claims 1, 2, 7-11, 17, 18, and 23-26, drawn to <u>radiolabeled</u> compounds of independent claim 1 wherein X is sulfur, classified in class 424, subclass 1.65.

Group (7) Claims 27-38, drawn to a method of detecting at least one A-beta species wherein X is oxygen, classified in class 424, subclass 9.1.

Group (8) Claims 27, 28, and 33-38, drawn to a method of detecting at least one A-beta species wherein X is nitrogen, classified in class 424, subclass 9.1.

Group (9) Claims 27, 28, and 33-38, drawn to a method of detecting at least one A-beta species wherein X is sulfur, classified in class 424, subclass 9.1.

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Group (10) Claims 39-48, drawn to a method of assessing an amyloid related disease wherein X is oxygen, classified in class 424, subclass 9.2.

Group (11) Claims 39-48, drawn to a method of assessing an amyloid related disease wherein X is nitrogen, classified in class 424, subclass 9.2.

Group (12) Claims 39-48, drawn to a method of assessing an amyloid related disease wherein X is sulfur, classified in class 424, subclass 9.2.

Group (13) Claims 49-57, drawn to a method of evaluating the effectiveness of therapy wherein X is oxygen, classified in class 424, subclass 9.1.

Group (14) Claims 49-57, drawn to a method of evaluating the effectiveness of therapy wherein X is nitrogen, classified in class 424, subclass 9.1.

Group (15) Claims 49-57, drawn to a method of evaluating the effectiveness of therapy wherein X is sulfur, classified in class 424, subclass 9.1.

**Note**: Claims appearing in more than one Group will only be examined to the extent that they read on the elected invention.

2. Groups (1), (2), and (3) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP 808.01). In the instant case, the different inventions while all encompassed under the very broad formula disclosed in independent claim 1 are unrelated because the formula contains the variable X. For example, X may form a 5-membered ring containing

oxygen, nitrogen, or sulfur which classify in difference classes and/or subclasses.

Hence, distinct groups of compounds are generated that are structurally unrelated to one another. As a result, a separate search of the art is necessary and such a search would impose a burden on the Examiner to search.

3. Groups (4 and 7), (4 and 10), (4 and 13), (5 and 8), (5 and 11), (5 and 14), (6 and 9), (6 and 12), and (6 and 15) are related as product and process and use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using the product (MPEP 806.05(h)). In the instant case, the products of Group (4) may be used in one of the methods of Groups (7), (10), or (13) above. The products of Group (5) may be used in one of the methods of Groups (8), (11), or (14) above. The products of Group (6) may be used in one of the methods of Groups (9), (12), and (15) above. Thus, each of the inventions is directed to products having distinct characteristics which may be used in a different process (e.g., in a method of detecting at least one A-beta species; a method of assessing an amyloid related disease; or a method of evaluating the effectiveness of therapy). Hence, a separate search of the art is necessary for each group and such a search would impose a serious burden on the Examiner to search even though some of the inventions classify in the same area.

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4. The inventions are distinct from each other for the reasons set forth above.

Hence, since these inventions are distinct and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

## **REJOINDER PARAGRAPH**

5. The Examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentably product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See

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"Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

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## **ELECTION OF SPECIES**

6. Claims 1-57 are generic to a plurality of disclosed patentably distinct species comprising various aromatic structures comprising a conjugated 6-membered carbon containing ring and a 5-membered ring optionally containing a nitrogen, oxygen, or sulfur atom. In addition, the aromatic structure is optionally radiolabeled. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

**Note**: Applicant is respectfully requested to elect a single disclose species from within the elected group. In addition, Applicant is respectfully requested to identify all of the variables (R1 and R2) associated with the elected species and the radiolabel, if applicable to the elected group.

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7. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

- 8. Due to the complexity of the restriction requirement, a telephone call was not made to request an oral election to the above restriction requirement.
- 9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).
- 10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
- 11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. 3:15 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Primary Examiner
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December 5, 2005